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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,593	01/10/2001	Michael G. Walker	PC-0025 CIP	9627

27904 7590 10/28/2003

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/758,593	WALKER, MICHAEL G.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

Claims 1, 5, 10, and 12 have been amended. Claims 1-12 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Withdrawn Rejections

The rejection of claim 5 under 35 U.S.C.§ 101 as set forth at page 3 of the previous office action (Paper No. 20, May 20, 2003) has been withdrawn in view of Applicants' amendment to the claim.

The rejection of claim 10 regarding the terms, "differentiation expression" and "a standard", under 35 U.S.C. §112, first paragraph for enablement as set forth in Paper No. 18 and Paper No. 20, has been withdrawn in view of Applicants' amendment to the claim.

The rejection of claims 1 and 3-12 under 35 USC § 112, 1st paragraph (New Matter), as set forth at pages 7-8 of the previous office action (Paper No. 20, May 20, 2003) has been withdrawn in view of Applicants' cancellation of claim 1, part c and part d and argument regarding claim 1, part b.

The rejection of claim 2 under 35 U.S.C. 112, first paragraph for description, as set forth 8-10 in Paper No. 20, has been withdrawn in view of Applicants' argument.

The rejection of claims 1 and 3-12 under 35 U.S.C.§ 112, 2nd paragraph as set forth in Paper No. 18 and Paper No. 20 has been withdrawn in view of Applicants' amendment to the claims.

The objection of claim 1 for minor informalities has been with drawn in view of Applicants' argument.

III. Objection to the Amendment to the Specification

The objection to the amendment filed in Paper No. 19 on April 2, 2003 under 35 U.S.C. 132 remains because it introduces new matter into the disclosure for the reasons set forth in Paper No. 20.

Applicants argue that the amendment that corrects amino acid numbering for the residues recited in these domains is found in the Sequence Listing for SEQ ID NO: 1 as well as in Figures 2A-2D. This has been fully considered but is not deemed to be persuasive because while SEQ ID NO: 1 is listed, there is no indication for the support of the four amended domains.

Applicant is required to cancel the new matter in the reply to this Office Action.

IV. Claim Rejections under 35 USC § 112, 1st paragraph (Enablement)

The rejection of claims 1-12 under 35 U.S.C. 112, first paragraph, as set forth 5-7 in Paper No. 20, remains.

At pages 6-8 of Applicants' response, Applicants argue that the fragments and

variants recited in the claims can be used as probes for the diagnosis of disease conditions associated with differential expression of Ankrd2V, in particular, clear cell sarcoma. Applicants further submit that the variants are enabled for producing transgenic cell lines or organisms which model human disorders and upon which potential therapeutic treatment may be tested, in particular for human clear cell sarcoma.

This has been fully considered but is not deemed to be persuasive because while the fragments of SEQ ID NO: 2 may be used as a probe for the diagnosis of clear cell sarcoma, the claimed variants and SEQ ID NO: 3 (a variant of SEQ ID NO: 2, not a fragment of SEQ ID NO: 2) may not be used as a probe for the diagnosis of disease conditions associated with differential expression of Ankrd2V because determining the specificity of hybridization is empirical by nature and the effect of mismatches is unpredictable, as taught by Wallace et al. (Methods Enzymol. 152:432-443, 1987) and Sambrook et al. (Molecular Cloning, A Laboratory Manual, 2nd Edition, 1989, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, page 11.47).

Secondly, the specification fails to provide sufficient information on how to produce naturally occurring variants of SEQ ID NO: 1 having at least 90% identity to SEQ ID NO: 1. There is no sufficient guidance or working example on how to make and use the variants in producing transgenic cell lines or organisms which model human disorders. With regarding the sequences recited in claim 2, the specification is silent on how to use these variants of a small portion of SEQ ID NO: 2 to produce transgenic cell lines or organisms which model a human disorder, in particular human clear cell sarcoma. Thus, one skilled in the art would not be able to practice the present invention

without undue experimentation.

In addition, claim 6 also remained rejected because its recitation of "A vector", which was suggested in the previous office action to be replaced by " An expression vector" to overcome this part of rejection.

V. Claim Rejections under 35 USC § 112, 1st paragraph (Description)

The rejection of claims 1 and 3-12 under 35 U.S.C. 112, first paragraph, as set forth 8-10 in Paper No. 20, remains.

Claims 1 and 3-12 are rejected because claim 1 (b) recites an isolated cDNA comprising a nucleic acid sequence encoding a naturally occurring variant of SEQ ID NO: 1 having at least 90% identity to the amino acid sequence of SEQ ID NO: 1. All other issues related to the description rejection have been resolved in view of Applicants' amendment to claim 1 and argument.

Beginning at page 10, Applicants argue, citing case law and "Guidelines for Examination of Patent Applications Under the 35 U.S. C. Sec. 112, para. 1", that the specification provides an adequate written description of the recited variants.

This has been fully considered, but is not deemed to be persuasive because the specification merely asserts "a variant having at least 85% identity to the amino acid sequence of SEQ ID NO: 1" (page 4, lines 22-23). There is no disclosure of such variants as Applicants argued. The variants of SEQ ID NO:2 (SEQ ID NOS: 7-10) disclosed on page 3 (lines 27-28) and page 11, share less than 19% sequence identity with SEQ ID NO: 2. The claims are drawn to a genus of nucleic acids that is defined only by partial sequence identity and the specification fails to provide sufficient

distinguishing identifying characteristics of the genus. Thus, Applicants were not in possession of the claimed invention at the time the application was filed.

Beginning at page 12, Applicants argue that the present claims specifically define the claimed genus through the recitation of chemical structure. This has been fully considered, but is not deemed to be persuasive because claim 1 (b) recites an isolated cDNA comprising a nucleic acid sequence encoding a naturally occurring variant of SEQ ID NO: 1 having at least 90% identity to the amino acid sequence of SEQ ID NO: 1. Thus, the claim is drawn to a genus of nucleic acids that is defined only by partial sequence identity to SEQ ID NO: 1, not by complete chemical structure as Applicants argued. The specification further fails to provide representative examples of such variants and methods of making such variants.

Beginning at page 14, Applicants argue that the present claims do not define a genus which is highly variant. Applicants submit that available evidence illustrates that the claimed genus is of narrow scope. This has been fully considered, but is not deemed to be persuasive because the specification is required to provide a sufficient description of the claimed subject matter regardless of the scope of a genus. Even if the claimed genus were as narrow as Applicants asserted, the specification would still be required to provide a sufficient description for the claimed genus. The mere recitation of percentage identity does not define the chemical structure of the genus and thus does not satisfy the description requirement under 35 U.S.C. 112, first paragraph. Furthermore, since there is no recitation of the biological functions of the variants in the

claim, the sequence homology alone does not limit that the claimed variants are functional variants of SEQ ID NO: 1.

Beginning at page 14, Applicants argue that the state of the art at the time of the present invention is further advanced that at the time of the Lilly and Fiers applications. This has been fully considered, but is not deemed to be persuasive because while the state of the art at the time of the present invention had been further advanced, the description requirement under 35 U.S.C. 112, first paragraph remains the same; that is the specification is required to provide sufficient description for the claimed subject matter. In the instant case, the specification fails to define the chemical structure of the genus, fails to describe the relation of the functions to structure of the genus, and fails to provide representative species of the genus. Therefore, Applicants were not in possession of the claimed variants at the time when the application was filed.

Finally, at page 15, Applicants summarize their arguments and submit that the specification satisfies the description requirement under 35 U.S.C. 112, first paragraph. The Examiner believes that the rejections should be maintained for the reasons set forth above.

VI. Claim Rejection under 35 USC § 112, 2nd paragraph

The rejection of claim 2 under 35 U.S.C.§ 112, 2nd paragraph as set forth at pages 11-12 of the previous office action (Paper No. 20, May 20, 2003) remains.

Applicants argue that since the claim recites a specific nucleic acid sequence of SEQ ID NO: 3, the metes and bounds of the claim element are unambiguously defined. This has been fully considered but is not deemed to be persuasive because the claim recites a fragment of SEQ ID NO: 2, whereas SEQ ID NO: 3 is not a fragment as the claim recites, rendering the claim indefinite.

VII. Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
October 21, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600